K110326

OCT 27 2011

OSRAM SYLVANIA

SP/Display Optic SSL

510(k) Summary

General Information

Date of Summary Preparation:	October 21, 2011
Name and Address of Manufacturer:	OSRAM SYLVANIA, Inc. 129 Portsmouth Avenue Exeter, New Hampshire, 03833
Company Contact Person:	Jack Burwick Product Marketing Manager, NAFTA SSL Telephone: 603-778-4555 Fax: 603-778-0674
Application Contact Person:	Marie A. Schroeder, MS, PT Principal Consultant Quintiles Consulting 1801 Rockville Pike, Suite 300 Rockville, MD 20852 Telephone: (301) 272-3286 Fax: (301) 272-0004

OSRAM SYLVANIA
129 Portsmouth Ave.
Exeter, NH 03833
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Trade Name:	OSRAM ITOS O-03100
Common Name:	Otoscope accessory lamp
Regulation Number:	21 CFR 874.4770
Classification Name:	Otoscope
Device Class:	Class I
Classification Panel:	Ear, Nose, and Throat
Product Code:	ERA
Predicate Device:	Welch Allyn Otoscope Diag. Model 20200 K781029 Welch Allyn Otoscope Models 20000, 21700, 25020 501(k) numbers unknown

Indications for Use:

The OSRAM ITOS O-03100 is intended to provide illumination of the ear canal and tympanic membrane for observation.

It is intended for over-the-counter (OTC) use.

Device Description:

The OSRAM ITOS O-03100 is an optional accessory lamp for use in compatible Welch Allyn otoscopes (Models 20000, 20200, 21700, 25020). The OSRAM ITOS O-03100 utilizes light emitting diode (LED) technology.

Performance Data:

Bench testing results for the key performance parameters were provided and demonstrated equivalent performance with respect to parameters critical to safety and effectiveness.

Durability tests performed included a drop test of the OSRAM ITOS O-03100 lamp by itself, a drop test of the otoscope system (lamp, otoscope head and 3.5VDC battery handle), and a pull test of the outer sleeve from the heat sink. The results from these three durability tests substantiate that the OSRAM ITOS O-03100 LED lamp is robust to real-world applications with respect to durability.

Prior to commercial distribution of the OSRAM ITOS O–03100, OSRAM Sylvania will conduct testing to the applicable sections of ASTM 4169 *Performance Testing of Shipping Containers and Systems* according to Assurance Level I and Criterion 1 to evaluate the product integrity and will assure conformance with Assurance Level I and Criterion 1 prior to commercial distribution.

Substantial Equivalence:

The OSRAM ITOS O-03100 (accessory otoscope lamp) and the predicate otoscope lamp have the same intended use and indications for use, i.e., they are intended to provide illumination of the ear canal and tympanic membrane for observation and both are intended for over-the-counter (OTC) use. While the OSRAM ITOS O-03100 utilizes a different fundamental technology, (LED technology) the new technological characteristics do not raise new types of safety or effectiveness questions. A comparison of the technological characteristics and bench testing results for the key performance parameters and durability demonstrated equivalent performance of the OSRAM ITOS O-03100 as compared to the predicate otoscope lamp with respect to parameters critical to safety and effectiveness.

OSRAM SYLVANIA followed IEC 62471:2006-07 Ed. 1 *Photobiological Safety of Lamps and Lamp Systems* for providing an optical radiation hazard evaluation (including blue light hazard exposure limits) resulting in an "EXEMPT group" for the ITOS O-03100 LED. In addition, the ITOS O-03100 was tested in ophthalmoscope heads in accordance to ISO 15004-2 *Ophthalmic Instruments – Fundaments requirements and test methods- Part 2: Light hazard protection* to determine risk of inadvertent use in an ophthalmoscope head. The resulting data show that the OSRAM ITOS O-03100 LED lamp (found to be in "group 2" per ISO 15004-2 classification) measured in all 3 ophthalmoscope heads produced values that are below the allowable limits for weighted corneal and lenticular ultra violet radiation irradiance, unweighted corneal and lenticular ultra violet radiation irradiance, unweighted corneal and lenticular infrared radiation irradiance, and weighted retinal visible and infrared radiation thermal radiance. Additional testing completed in accordance with section 5.5.16 for weighted retinal time-integrated radiance resulted in an exposure time limit of approximately 3 minutes for ophthalmoscope heads 11710 and 11720. The exposure time limit for the 11810 ophthalmoscope head was 9 minutes. Package labeling includes a cautionary note "not for use in ophthalmoscope attachments."

A clinical study was conducted regarding potential misdiagnoses due to possible different light characteristics associated with the OSRAM ITOS O-03100 LED lamp as compared to the predicate halogen lamp. There were no clinically meaningful differences in clinicians' perceptions of the topography of the ear drum and ear canal or in the diagnoses obtained with the ITOS O -03100 lamp and the predicate tungsten-halogen lamp. Therefore, the ITOS O -03100 lamp and the predicate tungsten-halogen lamp are effective when used in Welch Allyn otoscope heads.

Therefore, the OSRAM ITOS O-03100 is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

OCT 2 7 2011

Osram Sylvania, Inc.
c/o Marie A. Schroeder,
Principal Consultant, Quintiles Consulting
1801 Rockville Pik e, Suite 300
Rockville, MD 20852

Re: K110326
Trade/Device Name: OSRAM ITOS (Model O-3100)
Regulation Number: 21 CFR 874.4770
Regulation Name: Otoscope
Regulatory Class: Class I
Product Code: ERA
Dated: September 12, 2011
Received: September 13, 2011

Dear Ms. Schroeder:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K110326

Indications for Use

510(k) Number (if known): K110326

Device Name: OSRAM ITOS O-03100

Indications For Use:

The OSRAM ITOS O-3100 is intended to provide illumination of the ear canal and tympanic membrane for observation.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Rudy CRNP
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K110326